REMARKS

Claims 1, 5, and 8 have been amended. Claim 12, 17 and 18 remains as previously or originally presented. Claims 2 – 4, 9 – 11, 13 – 16, and 19 have been cancelled in previous responses. Claims 6 and 7 remain withdrawn.

Claims 1 and 12 have been rejected under 35 USC §103(a) as being unpatentable over EP 0952171 in view of '893 and in further view of US 5149747 in an earlier Office Action and that rejection is maintained in the present Office Action. The Examiner contends that EP '171 does not require the copolymer to be in a liquid state as asserted by the Applicant, but rather, references hydrogels which may be employed as stent coatings. Applicant has responded by asserting that the teachings of EP '171 cannot be used against the instant invention with or without the teaching of '747. First, the liquid polymers of '171 are expected to form hydrogels upon contacting wet biological tissue, as in the case of a vascular wall. Therefore, the active compositions applied onto the stent are to be liquid and packaging a liquid-coated sterilized stent prior to use is obviously impractical since the liquid coating cannot be maintained in a uniform state on the surface of the stent. This is quite different from a pre-formed solid coating that is already present on the stent before application. In response to the Applicant's arguments the Examiner cites a paragraph from U.S. 2003/0083740 that indicates that a formed liquid polymer can be used in coating stents. However, ignoring the fact that a liquid coating cannot be retained on the surface of a stent during deployment, a thin coating made of a liquid polymer as taught by EP '171 will not have the capacity of providing a

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sustained release of the drugs as it is taught by the instant invention because of the limited thickness of the liquid coating film and because of the high diffusion rate of the drug through the liquid vehicle (or a low melting solid that liquefies when present in the biological environment). Furthermore, the '893 reference is directed to a method for spherifying a sustained release ionic conjugate which contains a free carboxyl group-containing biodegradable polymer and a free amino group-containing drug, which are ionically bonded to each other. More specifically, that reference teaches the preparation of ionic conjugates in the form of microparticles and is silent regarding the use of these conjugates as components of any of the drug-containing coatings such as are taught by the present invention. Additionally, the '747 reference is directed to carboxyl ester hydroxyl-containing graft polymers for use as a binder in light-curable mixtures for the preparation of relief printing plates. This has nothing to do with the '893 reference nor with the present invention. It should be noted that the newly amended Claim 1 of the present case requires a coating with two pharmacologically different drugs, whereas the '893 reference is concerned with single drugs. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1, 8 and 12 have been rejected under 35 USC §103(a) as being unpatentable over EP '171 in view of US '747 and in further view of U.S. Patent No. 5,681,846. The Examiner argues that EP '171 discloses hydrogel polyester copolymers and their utility in providing a protective barrier to prevent post-surgical adhesion, etc., but fails to disclose introduction of at least one carboxyl side group by free-radically achieved maleation, which is taught by '747, and fails to disclose an antineoplastic drug such as paclitaxel,

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which is taught by '846. Applicant has argued that the '747 disclosure of the use of maleic anhydride to acylate the polymer is irrelevant to the teaching of the instant invention, noting that the use of maleic anhydride in the present invention leads to inserting a succinic acid residue into the polymer chain through a free radical reaction entailing the creation of a new C—C bond and not a C—O bond as is the case in '747. In response the Examiner has pointed out that such limitation was not found in the claims. However, the claims have been amended to clarify the origin of the carboxyl side groups, which inherently are linked to the polymer chain by a C-C bond. Furthermore, the '740 reference is directed to one bioactive compound and not two as in the newly amended Claim 1 of the instant invention. For these reasons and those set forth above with respect to the initial rejection of claims 1 and 12, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1, 8, 12 and 17 – 18 have been rejected under 35 USC §103(a) as being unpatentable over EP '171 in view of US '747 in further view of US '846, in further view of US 5304121. The Examiner argues that the primary reference and the first two secondary references teach the present invention but fail to teach a metallic endovascular stent coated with the hydrogel composition, which is taught by US '121. Applicant has argued that while the Examiner was able to assemble these four references based on the hindsight gained from a review of the present specification, no combination of the four anticipates or renders obvious the present invention. The Examiner has responded by arguing that reliance on a large number of references does not, without more, weigh against the obviousness of the invention. However, no combination of these four

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references renders the present claims obvious. The '171 reference requires liquid coatings; the '747 reference is directed to a method for delivering graft polymer coating that is not absorbable (or biodegradable) and therefore is totally different from the absorbable coating of the instant invention; the '846 reference is concerned with paclitaxel only and formulations for its extended stability where the formulations are based on liquid carriers (not solid as in the instant invention); and the '121 reference is directed to catheters and methods for delivering drugs to tissue at desired locations. That is, the delivery system of the '121 reference is specifically designed for a preselected aqueous, mobile drug with the aid of catheters whereas the carriers of the instant invention are water-insoluble stent coatings. Requirements for delivery using a catheter with limited surface area are substantially different from those for stents. Thus, is it requested that the Examiner reconsider and withdraw the present rejection.

Accordingly, it is submitted that the present application is in condition for allowance and such action is respectfully requested.

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